

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:  
Jaap Van Der Louw et al.

Application No.: 10/584,006

Conf. No.: 8561

Filed: June 22, 2006

Art Unit: 1617

For: STEROIDS HAVING A MIXED  
ANDROGENIC AND PROGESTAGENIC  
PROFILE

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Examiner: Paul Zarek

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**DETERMINATION UNDER 37 CFR §1.705(B)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Allowability issued March 17, 2009, Applicants respectfully request reconsideration of the Patent Term Adjustment of 384 days noted on page 3 of the Notice, and request that it be corrected to 476 days. The present request, being filed along with the issue fee transmittal, is timely. 37 C.F.R. §1.705(b).

The office is authorized to charge deposit account no. 50-4205 the required fees set forth in 37 C.F.R. §1.18(e) (**\$200**) and 37 C.F.R. §1.705(b)(1).

Applicants respectfully submit that the correct Patent Term Adjustment is 476 days. The basis upon which Applicants request reconsideration of the patent term adjustment is as follows (for details see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program):

1. Under the 14-Month Rule [(§1.703(a))] the present application was filed on June 22, 2006 and the First Action was mailed September 9, 2008. Accordingly under the 14-Month Rule the period of adjustment for the USPTO delay is 384 days which is also reflected in the Patent Term Adjustment History.

2. However, should a patent issue after June 22, 2009 (three years from the June 22, 2006 filing date of the application), adjustment of the patent term pursuant to 35 U.S.C. §154 (b)(1)(B) [(§1.703(b), stipulating issuance of a patent within three years of the application filing date] would be implicated based upon the Wyeth *et al.* v. Dudas ruling recently published (No. 07-1492 D.D.C. September 30, 2008). Assuming an estimated issue date of September 22, 2009, it is respectfully submitted that the period of adjustment for USPTO delay (in accordance with the ruling in Wyeth *et al.* v. Dudas) begin on the day after the three year period, June 22, 2009 (see attached AIPA Term Calculation Report utilizing Professor Kayton's patent Term® on line program) and end on the aforementioned estimated issue date, which is a period of adjustment due to USPTO delay of 92 days.

5. Accordingly, Applicants respectfully submit that the patent term adjustment period is the total days debited the USPTO, 476 days, minus the total number of days debited Applicants, 0 days, to yield a total patent term adjustment of 476 days (see attached AIPA Term Calculation Report utilizing Professor Kayton's Patent Term on line program).

The present application is not subject to a terminal disclaimer. [37 C.F.R. §1.705(b)(2)(iii)].


Applicants reserve the right, under 37 C.F.R. §1.705(d), to request further revisions to the patent term adjustment, should the Office fail to note the revised patent term adjustment on the face of any patent issuing from the present application, or fail to timely issue any patent issuing from the present application.

Early and favorable action is earnestly solicited.

Dated: June 17, 2009

Respectfully submitted,

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By   
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Attachment

99131\_1.DOC



APPLICATIONS

PROSECUTOR HISTORY

AIRPAT TERM CALC

TERM ANALYSIS

Docket Number: **2003.810US**

## APPLICATION INFORMATION

Docket Number:	2003.810US	User Name:	Hess, Susan
Application Number:	10/584,006	Firm/Company Name:	Organon, a part of Schering-Plough
Filing Date:	12/15/2004	User Comments:	
Title/Inventor(s):	STEROIDS HAVING A MIXED ANDROGENIC AND PROGESTAGENIC PROFILE; Jaap Van Der Louw , Oss, (NL)	Calculation Generated:	06/11/2009 04:59:11 PM ET

## AIPA TERM CALCULATION SUMMARY

Earliest Referenced Application under 35 USC § 120, 121, or 365 (c):	12 / 15 / 2004
International Filing Date:	12 / 15 / 2004
Net Adjustment <b>Credits</b> :	476 Days
Net Adjustment <b>Debits</b> :	0 Days
Patent Term Adjustment:	476 Days
AIPA Patent Term End Date:	04 / 05 / 2026 <sup>(1)</sup>
<sup>(1)</sup> Assumes payment of all maintenance fees, no intervening acts, and no 35 USC 156 regulatory extensions. Terminal disclaimer(s) filed in this case, if any, may result in an earlier term end date. Without adjustment, the term would end on 12/15/2024.	

COMPARISON TO USPTO PAIR PTA TAB<sup>(2)</sup>  
(Based on PAIR Data from 06/11/2009)

	PAIR PTA Tab	Your Calculation	Comparison
Credit Days (USPTO Delay):	384	476	✗
Debit Days (Applicant Delay):	0	0	MATCH ✓
Total Patent Term Adjustment Days:	384	476	✗

(2) Comparison is shown for USPTO Delay, Applicant Delay, and Total Patent Term Adjustment fields displayed on USPTO PAIR Patent Term Adjustments (PTA) tab on 06/11/2009. See the full PAIR PTA tab, file wrapper (e.g., Notice of Allowance, PTA-related petitions), and issued patent for complete information on USPTO-calculated PTA.

RULE CALCULATION SUMMARY <sup>(3)</sup>						
	Event	Rule Invoked	Related Event	Exclusion Days <sup>(4)</sup>	Debit Days <sup>(5)</sup>	Credit Days <sup>(6)</sup>
A	06/22/2006 National Stage Commenced under 35 USC 371(b) or (f)	<p><b><u>3-Year PTO Issue of Patent</u></b></p> <p>PTO must issue a patent within 3 years (not including exclusions) after the date on which the application was filed under 35 USC 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application. Period of adjustment (credits) begins on the day after the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 USC 371(b) or (f) in an international application and ending on the date a patent was issued, but not including the sum of the listed exclusionary periods. 35 USC 154(b)(1)(B); 37 CFR 1.702(b), 1.703(b).</p> <p>You have elected to analyze this rule without applying the USPTO 37 CFR § 1.703 (f) Actual Delay limitation in determining Credit Days under this rule. This is consistent with DC District Court ruling in Wyeth et al. v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).</p>	<p><i>Issue Date:</i></p> <p>09/22/2009 Issue Date</p>			92
B	06/22/2006 Application Fulfilled Requirements of 35 USC 371	<p><b><u>14-Month PTO First Action</u></b></p> <p>PTO must mail a notification under 35 USC 132 or a notice of allowance under 35 USC 151 not later than 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 in an international application. Period of adjustment (credits) begins on the day after the date that is 14 months after the date on which the application was filed under 35 USC 111(a) or fulfilled the requirements of 35 USC 371 and ending on</p>	<p><i>First PTO Action:</i></p> <p>09/09/2008 Restriction / Election-of-Species</p>			384

		the date of mailing of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(i); 37 CFR 1.702(a)(1), 1.703(a)(1).				
C	09/09/2008 Restriction / Election-of- Species	<p><b><u>3-Month Applicant Response to Notice or Action</u></b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	Applicant Response:	10/09/2008 Response to Election-of- Species / Restriction Filed	0	
D	10/09/2008 Response to Election-of- Species / Restriction Filed	<p><b><u>4-Month PTO Response to Applicant Reply</u></b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2),(3).</p>	PTO Response:	01/06/2009 Non-final Action	0	
		<p><b><u>3-Month Applicant Response to Notice or Action</u></b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3</p>				

E	01/06/2009 Non-final Action	<p>months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR 1.704(b).</p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	<p><i>Applicant Response:</i></p> <p>01/13/2009 Reply after Non-final Action under 37 CFR 1.111</p>	0	
F	01/13/2009 Reply after Non-final Action under 37 CFR 1.111	<p><b>4-Month PTO Response to Applicant Reply</b></p> <p>PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 or in compliance with 37 CFR 1.113(c) was filed and ending on the mailing date of either an action under 35 USC 132, or a notice of allowance under 35 USC 151, whichever occurs first. 35 USC 154(b)(1)(A)(ii); 37 CFR 1.702(a)(2), 1.703(a)(2), (3).</p>	<p><i>PTO Response:</i></p> <p>03/17/2009 Notice of Allowance under 35 USC 151</p>	0	
G	03/17/2009 Notice of Allowance under 35 USC 151	<p><b>3-Month Applicant Response to Notice or Action</b></p> <p>Period of adjustment (credits) shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action making any rejection, objection, argument, or other request, beginning on the day after the date that is 3 months after the date of mailing or transmission of the Office communication and ending on the date the reply was filed. The period, or shortened statutory period, for reply set in the action or notice has no effect on this deadline. 35 USC 154 (b)(2)(C)(ii); 37 CFR</p>	<p><i>Applicant Response:</i></p> <p>06/17/2009 Issue Fee Payment</p>	0	

		<p><b>1.704(b).</b></p> <p>Where applicant shows, in spite of all due care, applicant was unable to respond within the 3-month period, all or part of adjustment may be reinstated for up to 3 additional months. 35 USC 154(b)(3)(C); 37 CFR 1.705(c).</p> <p>You have indicated that no 1.705(c) Showing of Due Care was made.</p>	under 35 USC 151			
H	<p>06/17/2009 Issue Fee Payment under 35 USC 151</p>	<p><b>4-Month PTO Issue of Patent</b></p> <p>PTO must issue a patent not later than 4 months after the date on which the issue fee was paid under 35 USC 151 and all outstanding requirements were satisfied. The period of adjustment (credits) begins on the day after the date that is 4 months after the date the issue fee was paid and all outstanding requirements were satisfied and ends on the day the patent issues. 35 USC 154(b)(1)(A)(iv); 37 CFR 1.702(a)(4), 1.703(a)(6).</p>	<p><i>Issue Date:</i></p> <p>09/22/2009 Issue Date</p>			0
<b>Total Exclusion, Debit, and Credit Days:</b>				0	0	476
<b>Overlap Days<sup>(7)</sup>:</b>				0	0	0
<b>Net Exclusion, Debit, and Credit Days:</b>				0	0	476
<b>Patent Term Adjustment Days<sup>(8)</sup>:</b>						476
<p><sup>(3)</sup>Calculations of Debit, Credit, and Exclusion Days are determined by the rule assignments, assignments of related events, and analysis options in the Apply Term Rules tab. The patent professional using this system is responsible for reviewing and updating the Apply Term Rules tab to ensure all data is complete, correct, and consistent with their judgment and interpretation of applicable legal authority.</p> <p><sup>(4)</sup>Exclusion Days are periods which are not included in determining the end of the 3-year period after the date on which the application was filed under 35 USC 111(a), or the national stage commenced under 35 USC 371(b) or (f) in an international application, used to determine credits under the 3-Year PTO Issue of Patent rule. See 35 USC 154(b)(1)(B)(i)-(iii); 37 CFR 1.702(b)(1)-(5), 1.703(b)(1)-(4).</p> <p><sup>(5)</sup>Debit Days are days where grounds for reduction of period of adjustment of patent term exist. See, e.g., 37 CFR 1.704. Debit Days are sometimes referred to as Applicant Delay.</p> <p><sup>(6)</sup>Credit Days are days where grounds for adjustment of patent term exist. See, e.g., 37 CFR 1.702, 1.703. Credit Days are sometimes referred to as USPTO Delay.</p> <p><sup>(7)</sup>To the extent credit periods overlap other credit periods, debit periods overlap other debit periods, or exclusion periods overlap other exclusion periods, overlaps are subtracted so that each calendar day generates at most one credit day, one debit day, and one exclusion day.</p> <p><sup>(8)</sup>Patent Term Adjustment Days equals Net Credit Days minus Net Debit Days, but is not less than zero.</p>						

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10/584,006

STEROIDS HAVING A MIXED ANDROGENIC AND PROGESTAGENIC PROFILE

06-11-  
2009::17:08:00**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/584,006

Filing or 371(c) Date:	06-22-2006	USPTO Delay (PTO) Delay (days):	384
Issue Date of Patent:	-	Three Years:	
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	0
Post-Issue Petitions (days):	+0	Total PTA (days):	384
USPTO Adjustment(days):	+0	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
03-17-2009	Mail Notice of Allowance		
03-12-2009	Document Verification		
03-12-2009	Notice of Allowance Data Verification Completed		
03-12-2009	Case Docketed to Examiner in GAU		
03-12-2009	Examiner's Amendment Communication		
02-23-2009	Date Forwarded to Examiner		
01-13-2009	Response after Non-Final Action		
01-06-2009	Electronic Review		
01-06-2009	Email Notification		
01-06-2009	Mail Non-Final Rejection		
12-22-2008	Non-Final Rejection		
12-09-2008	Case Docketed to Examiner in GAU		
03-12-2007	Information Disclosure Statement considered		
10-17-2008	Date Forwarded to Examiner		
10-09-2008	Response to Election / Restriction Filed		
09-09-2008	Electronic Review		
09-09-2008	Email Notification		
09-09-2008	Mail Restriction Requirement	384	
09-04-2008	Requirement for Restriction / Election	↑	
07-20-2008	Case Docketed to Examiner in GAU	↑	
03-11-2008	Case Docketed to Examiner in GAU	↑	
01-03-2008	Change in Power of Attorney (May Include Associate POA)	↑	
09-24-2007	IFW TSS Processing by Tech Center Complete	↑	
03-12-2007	Reference capture on IDS	↑	
03-12-2007	Information Disclosure Statement (IDS) Filed	↑	
06-22-2006	Request for Foreign Priority (Priority Papers May Be Included)	↑	
06-22-2006	Preliminary Amendment	↑	
07-05-2007	PG-Pub Issue Notification	↑	
06-05-2007	Correspondence Address Change	↑	
03-12-2007	Information Disclosure Statement (IDS) Filed	↑	
04-18-2007	Application Dispatched from OIPE	↑	

06-22-2006	371 Completion Date	↑
03-27-2007	Sent to Classification Contractor	↑
03-28-2007	Notice of DO/EO Acceptance Mailed	↑
07-20-2006	Cleared by OIPE CSR	↑
06-22-2006	Initial Exam Team nn	↑

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